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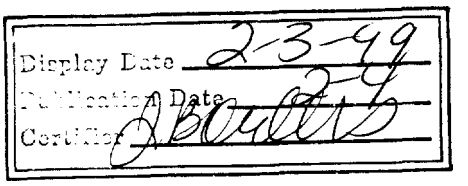
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration



21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Bacitracin Methylene Disalicylate and Roxarsone With Monensin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Alpharma Inc. The supplemental NADA provides for using approved single ingredient bacitracin methylene disalicylate (BMD), monensin, and roxarsone Type A medicated articles to make an additional use level of BMD in Type C medicated broiler chicken feeds.

EFFECTIVE DATE: *(Iii.sert date of publication in the* **Federal Register.)**

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pi., Rockville, MD 20855, 301-827-7575.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed supplemental NADA 116-088 that provides for combining approved BMD® (10, 25, 30, 50, 60, or 75 grams per pound (g/lb) BMD), Coban® (45 or 60 g/lb monensin sodium), and 3–Nitro® (45.4, 90, 227, or 360 g/lb roxarsone) Type A medicated articles to make Type C medicated broiler chicken feeds containing 100 to 200 g/ton(t) BMD, 90 to 110 g/t monensin sodium, and 22.7 to 45.4 g/t roxarsone. The BMD, monensin, and 22.7 to 34 g/t roxarsone Type C medicated feeds are used as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to BMD; as an aid in the prevention of

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coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and for increased rate of weight gain and improved feed efficiency. The B\ ID. monensin, and 22.7 to 45.4 g/t roxarsone Type C medicated feeds arc used as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to BMD; as an aid in the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and for increased rate of weight gain. The supplemental NADA is approved as of December 24, 1998, and the regulations are amended in 21CFR 558..355 by revising paragraph (b)(11) and adding paragraphs (f)(1)(xxvi) and (f)(1)(xxvii) to reflect the approval. The basis for approval is discussed in the freedom of information summary,

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of the application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane. rm.1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 C'FR 25.33(a)(2) that [his action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore. neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Pm-t 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegate to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, **371.**

2. Section 558.355 is amended in paragraph (b)(1) by deleting "and (xxv)" and adding in its place "(xxv), (xxvi), and (xxvii)" and by adding paragraphs (f)(1)(xxvi) and (f)(1)(xxvii) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(1) * * *

(xxvi) *Amount per ton.* Monensin **90 to** 110 grams plus bacitracin 100 to 200 grams and roxarsone 22.7 to 34.0 grams.

(*a*) *Indications for use.* As an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin methylene disalicylate; as an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati*; for increased rate of weight gain and improved feed efficiency.

(*b*) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Use as sole source of organic arsenic. Withdraw 5 days before slaughter. Do not feed to laying hens. To control necrotic enteritis, start medication at first clinical signs of disease. The dosage range permitted provides for different levels based on [he severity of infection. Use continuously for 5 to 7 days or as long as clinical signs persist, then reduce dosage to prevention level. Animals should have access to drinking water at all times. Drug overdosage or lack of water may result in leg weakness. As roxarsone and bacitracin methylene disalicylate provided by No. 046573 in § 5 1O.6OO(C) of this chapter.

(xxvii) *Amount per fen.* Monensin 90 to 110 grams plus bacitracin 100 to 200 grams and roxarsone 22.7 to 45.4 grams.

(*a*) *Indications for use.* As an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin methylene disalicylate; as an aid

in the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*; for increased rate of weight gain.

(*b*) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Use as sole source of organic arsenic. Withdraw 5 days before slaughter. Do not feed to laying hens. To control necrotic enteritis, start medication at first clinical signs of disease. The dosage range permitted provides for different levels based on the severity of infection. Use continuously for 5 to 7 days

or as long as clinical signs persist, then reduce dosage to prevention level. Animals should have access to drinking water at all times. Drug overdosage or lack of water may result in leg weakness. As roxarsone and bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter.

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Dated: 1/13/99...
January '13, 1999

Andrew J. Beaulieu
Acting Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

[FR Doc. 99-'? '?'?'7 Filed??-??-99;8:45am]

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